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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,958	05/29/2001	Henry Yue	PC-0041 CIP	2217

27904 7590 04/04/2003

INCYTE CORPORATION (formerly known as Incyte  
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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,958

Applicant(s)

YUE ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **Detailed Action**

#### **Election/Restriction**

1. Applicant's election with traverse of SEQ ID NO:2 encoding SEQ ID NO:1 in Paper No. 11, filed on 13 December 2002 is acknowledged. The traversal is on the grounds that the Examiner has not established that there would be a serious burden of search in examining all of the recited sequences. Since SEQ ID Nos: 3-8 are disclosed as being fragments of SEQ ID No: 2, they share common structural property with SEQ ID NO:2 and a single search would find all of these sequences.

This ground of traversal has been fully considered but is not deemed persuasive, because, although Applicants assert that SEQ ID Nos: 3-8 are fragments of SEQ ID No: 2, they do not disclose exactly how these sequences are related to one another. Therefore, contrary to Applicants' assertion a single search would not reveal art pertinent to all of the recited sequences. Thus, searching more than one product would pose undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

The elected invention is Group I (claims 1-6, SEQ ID NO:1, 2). Thus, claims 1-6 are under consideration, (claim 2 will be searched and examined in so far as it relates to SEQ ID NO:2). Claims 7-20 are withdrawn from prosecution as being drawn to a non-elected invention.

#### **2. Priority**

Instant application is a continuation in part of application serial no. 09/325,993, filed on 06/04/99, which is a divisional of 08/948,197 filed on 10/09/97. Based on an

inspection of the parent application, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no.

09/325,993, filed 06/04/99, because, the instant specification is significantly different from that of the parent application. Accordingly, the subject matter defined in instant claims 1-6, and SEQ ID NO:1 and 2 are afforded the effective filing date of 05/29/01 which is the filing date of the current application.

**Specification**

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested "nucleic acid encoding a progesterone receptor complex p23-like protein".

**Claim objections**

4. Claim 2 is objected to because of the following informalities:

Claim 2 is objected to because it recites non-elected SEQ ID Nos. Appropriate correction is required.

**Claim Rejections - 35 U.S.C. § 101/112**

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-6 of the instant invention are directed to an isolated nucleic acid encoding a protein having the amino acid

Application/Control Number: 09/867,958

Art Unit: 1647

sequence set forth in SEQ ID NO:1, said nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:2, a vector comprising said nucleic acid, a host cell comprising said vector and a method of producing the encoded protein. The specification describes the claimed nucleic acid as encoding a progesterone receptor complex p23-like protein which shares 39% identity to human p23 (see page 9, lines 11-31). Instant specification states that the claimed sequence is expressed in various libraries, at least 67% of which are immortalized or cancerous and at least 33% of which involve immune response and that the protein of the instant invention is also expressed in neurological, respiratory, female reproductive, gastrointestinal and hematopoietic/immune tissues, (see page 9, line 31 through page 10, line 7).

However, instant specification does not disclose any information regarding physiologic or functional characteristics of the protein encoded by the claimed nucleic acid. Although, *in vitro*, p23 has been attributed chaperone-like properties and seems to be required for the folding of number of cell regulatory proteins, including steroid hormone receptors, the function of P23 is not yet understood, (see Weikl, page 685, bottom of column 1 and page 686, column 1, second paragraph). Furthermore, the fact that the protein encoded by the nucleic acid of the instant Application shares 39% identity with human p23 does not provide enough information regarding the physiological role of this protein. One of ordinary skill in the art would not reasonably expect a protein, which only shares 39% identity to another protein to possess the same activity with any degree of predictability. This would equate to mutation of a protein such that it is only 39% identical to the

(b) the invention was patented or described in a printed publication in a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 1-6 are rejected under 35 U.S.C. 102(a)(1) as anticipated by Yue et al (WO 99/19483 issued, 1999/09/23).

Yue et al disclose an isolated polynucleotide comprising a nucleotide sequence of the instant SEQ ID NO:1, an expression vector comprising said polynucleotide, a host cell comprising said vector of producing the encoded protein, (see claims). Attached copies of the comparison of SEQ ID NOs:1 of the instant invention and the sequences of the reference sequences 'A and B' respectively).

Therefore Yue et al reference clearly anticipates the invention in the absence of any evidence to the contrary.

#### Conclusion

No claim is allowed.

#### Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:30 AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

native protein and still hope that it would retain the function of the native protein. The claimed invention is directed to nucleic acid and its encoded protein of as yet undetermined function or biological significance. The specification does not establish a nexus between the protein of the instant invention and any disease or pathological condition. Applicants on provide the structure of the claimed nucleic acid and the protein it encodes, and an expression pattern, however, this is not sufficient to establish a specific or substantial utility for the claimed invention.

4b. Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not define the physiological role of the progesterone receptor complex p23-like protein of the instant invention, neither does it establish a link between this protein and a disease or a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that is insufficient to establish a specific or substantial utility for the claimed invention.

#### Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate portion of 35 U.S.C. 102 that forms the basis for the rejections made in this Office action:


A person shall be entitled to a patent unless -

Application/Control Number: 09/867,958

Page 7

Art Unit: 1647

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
27 March 2003

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



A DOCPHOENIX

## APPL PARTS

**IMIS** \_\_\_\_\_  
Internal Misc. Paper

**LET** \_\_\_\_\_  
Misc. Incoming Letter

**371P** \_\_\_\_\_  
PCT Papers in a 371 Application

**A...** \_\_\_\_\_  
Amendment Including Elections

**ABST** \_\_\_\_\_  
Abstract

**ADS** \_\_\_\_\_  
Application Data Sheet

**AF/D** \_\_\_\_\_  
Affidavit or Exhibit Received

**APPENDIX** \_\_\_\_\_  
Appendix

**ARTIFACT** \_\_\_\_\_  
Artifact

**BIB** \_\_\_\_\_  
Bib Data Sheet

**CLM** \_\_\_\_\_  
Claim

**COMPUTER** \_\_\_\_\_  
Computer Program Listing

**CRFL** \_\_\_\_\_  
All CRF Papers for Backfile

**DIST** \_\_\_\_\_  
Terminal Disclaimer Filed

**DRW** \_\_\_\_\_  
Drawings

**FOR** \_\_\_\_\_  
Foreign Reference

**FRPR** \_\_\_\_\_  
Foreign Priority Papers

**IDS** \_\_\_\_\_  
IDS Including 1449

**NPL** \_\_\_\_\_  
Non-Patent Literature

**OATH** \_\_\_\_\_  
Oath or Declaration

**PET** \_\_\_\_\_  
Petition

**RETMAIL** \_\_\_\_\_  
Mail Returned by USPS

**SEQLIST** \_\_\_\_\_  
Sequence Listing

**SPEC** \_\_\_\_\_  
Specification

**SPEC NO** \_\_\_\_\_  
Specification Not in English

**TRNA** \_\_\_\_\_  
Transmittal New Application

**CTNF** \_\_\_\_\_  
Count Non-Final

**CTRS** \_\_\_\_\_  
Count Restriction

**EXIN** \_\_\_\_\_  
Examiner Interview

**M903** \_\_\_\_\_  
DO/EO Acceptance

**M905** \_\_\_\_\_  
DO/EO Missing Requirement

**NFDR** \_\_\_\_\_  
Formal Drawing Required

**NOA** \_\_\_\_\_  
Notice of Allowance

**PETDEC** \_\_\_\_\_  
Petition Decision

## OUTGOING

**CTMS** \_\_\_\_\_  
Misc. Office Action

**04-04-03** 1449 / \_\_\_\_\_  
Signed 1449

**892** \_\_\_\_\_  
892

**ABN** \_\_\_\_\_  
Abandonment

**APDEC** \_\_\_\_\_  
Board of Appeals Decision

**APEA** \_\_\_\_\_  
Examiner Answer

**CTAV** \_\_\_\_\_  
Count Advisory Action

**CTEQ** \_\_\_\_\_  
Count Ex parte Quayle

**CTFR** \_\_\_\_\_  
Count Final Rejection

## INCOMING

**AP.B** \_\_\_\_\_  
Appeal Brief

**C.AD** \_\_\_\_\_  
Change of Address

**N/AP** \_\_\_\_\_  
Notice of Appeal

**PA..** \_\_\_\_\_  
Change in Power of Attorney

**REM** \_\_\_\_\_  
Applicant Remarks in Amendment

**XT/** \_\_\_\_\_  
Extension of Time filed separate

## Internal

**SRNT** \_\_\_\_\_  
Examiner Search Notes

**CLMPTO** \_\_\_\_\_  
PTO Prepared Complete Claim Set

**ECBOX** \_\_\_\_\_  
Evidence Copy Box Identification

**WCLM** \_\_\_\_\_  
Claim Worksheet

**WFEE** \_\_\_\_\_  
Fee Worksheet

## File Wrapper

**FWCLM** \_\_\_\_\_  
File Wrapper Claim

**IIFW** \_\_\_\_\_  
File Wrapper Issue Information

**SRFW** \_\_\_\_\_  
File Wrapper Search Info